



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 26, 2015

Scientia Vascular, LLC
% Mr. Mark Job
Third Party Reviewer
Regulatory Technology Services, LLC
1394 25th St., NW
Buffalo, MN 55313

Re: K143398
Trade/Device Name: Plato MICROCATH 27B Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, KRA
Dated: June 5, 2015
Received: June 12, 2015

Dear Mr. Job,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K143398

Device Name
Plato MICROCATH® 27B Microcatheter

Indications for Use (Describe)

The Plato MICROCATH 27B Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents to the peripheral system. The catheter is not intended for use in either the coronary or neuro vasculature.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Bram D. Zuckerman -S
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510(K) SUMMARY (21 CFR 807.92)

**SCIENTIA VASCULAR LLC
PLATO MICROCATH® 27B MICROCATHETER**

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Date Prepared: October, 2014

Trade Name: Plato MICROCATH® 27B Microcatheter

Common Name: Microcatheter

Classification Name: Diagnostic Intravascular Catheter per 21 CFR 870.1200, DQO
Continuous Flush Catheter per 21 CFR 870.1210, KRA

Predicate Devices: ev3 Marksman™ Catheter, K111490, K091559
Scientia Vascular, LLC Plato MICROCATH 27 Microcatheter, K121734

Device Description: The Plato MICROCATH® 27B Microcatheter is a single lumen microcatheter constructed with a flexible polymer shaft of varying stiffness to aide in accessing vasculature. The catheter is designed to be used with a guide catheter and a steerable guidewire for accessing the vasculature. The proximal end of the catheter has a diameter of 3.4F, tapering to a distal OD of 3.2F, which can be inserted into a 5F guide catheter. The inner diameter is constant throughout the shaft length and accommodates up to a 0.025" guidewire. The catheter is 150 cm in length with a straight tip configuration which can be steam-shaped to the doctor's preferred shape. A steam shaping mandrel is included in the packaging. The microcatheter has hydrophilic coating on the outer distal shaft to

reduce friction during manipulation in vessels and has one radiopaque tip marker to facilitate fluoroscopic visualization.

Indications for Use: The Plato MICROCATH 27B Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents to the peripheral system. The catheter is not intended for use in either the coronary or neuro vasculature.

The indications for use are identical to those of the ev3 Marksman Catheter, with the exception that the Marksman Catheter is also indicated for neurovascular and coronary use. The MICROCATH 27B has not been evaluated for these indications. This difference does not affect the safety and effectiveness of the device for its intended application in the peripheral vasculature.

**Technological
Characteristics:**

The Plato MICROCATH 27B Microcatheter is a single lumen, variable stiffness microcatheter designed to provide increased flexibility for accessing the vasculature. The proximal end of the catheter incorporates a polycarbonate Luer adapter to facilitate the attachment of accessories. The distal end has a polymeric skeletal support for improved distal navigation. The device is compatible with 5 F or larger guiding catheters and can be advanced over guidewires up to 0.025" in diameter. The distal shaft has a hydrophilic coating for lubricity and is shapeable.

The technological characteristics are comparable to the predicate device, the ev3 Marksman Catheter. The Marksman Catheter is a single lumen, variable stiffness catheter designed to be introduced over a steerable guidewire into the vasculature. The proximal end of the catheter incorporates a standard Luer adapter to facilitate the attachment of accessories. The distal end has a coiled support structure and the device is compatible with 4 F or larger guiding catheters and can accommodate guidewires up to 0.021" in diameter. The Marksman catheter has an embedded braid to impart strength and stiffness to the proximal end and a coiled structure in the distal end. The Plato MICROCATH 27B Microcatheter uses an embedded stainless steel braid on the proximal end and uses a polymeric skeletal support in the distal end to support the lumen and prevent collapse in tortuous vessels. The outer surface of the distal end of the catheter is coated to increase lubricity, and the catheter is shapeable. The technological differences between the Plato MICROCATH 27B Microcatheter and the ev3 Marksman Catheter do not raise new questions of safety or efficacy.

The technological differences between the Plato MICROCATH 27B and the marketed Plato MICROCATH 27 models include 1) the rigid hypotube at the proximal end has been replaced with a braided coil to increase flexibility, 2) the outer diameter has been reduced to allow the microcatheter to be advanced into small vasculature, 3) the distal end of the catheter has been modified with a replacement thermoplastic elastomer, a polymer microstructure and alternate lubricious coating to improved usability, 4) a polycarbonate hub replaces the polymethylpentene hub based on physician preferences and, 5) a platinum marker replaces the platinum marker coil. These technological differences do not raise new questions of safety or efficacy.

Non-Clinical

Performance Data: Non-clinical testing included biocompatibility testing of the assembled device as defined in ISO 10993, functional testing as defined in ISO 10555-1:2013, the FDA guidance for Short-Term and Long-Term Intravascular Catheters, dated March 16, 1995 and the FDA Special Controls Document for PTCA Catheters (Part VIII, section 13), dated September 8, 2010. Functional testing performed on the proposed device included:

Test	Test Method Summary	Results
Cytotoxicity	MEM elution test per ISO 10993-5.	Non-cytotoxic. Test article scores were 0 at 48 hours.
Sensitization	Kligman Maximization per ISO 10993-10	Negative for dermal sensitization. Test articles sensitization scores were all 0.
Irritation/Intracutaneous Reactivity	Irritation/Intracutaneous reactivity test per ISO 10993-10.	Non-irritating. Extracts of the test article did not show a significantly greater biological reaction than sites injected with control article.
Acute systemic toxicity	Acute systemic injection test in mice per ISO-10993-11.	Non-toxic. Test articles showed no toxicity or animal weight loss for both cottonseed oil and saline extracts for 72 hour test period.
Materials mediated pyrogenicity	Rabbit pyrogen test per ISO 10993-11.	Non-pyrogenic. No increases in individual temperatures.
Hemocompatibility – hemolysis by direct contact and extract	Direct contact method and extract method per modified ASTM 758-08.	Non-hemolytic. Corrected hemolysis index was 0.15% by direct method, 0.23% by extract.

Test	Test Method Summary	Results
Partial Thromboplastin Time	Partial thromboplastin time per ASTM F2382.	Both test article and predicate were minimal activators. Difference in clotting times between test article and predicate was 3 seconds.
Complement activation of C3a and SC5b-9	C3a and SC5b-9 levels tested per ISO 10993-4.	Complement activation by the test article was less than that of the predicate device.
Thrombogenicity in Dogs	Thrombogenicity test in dogs per ISO 10993-4.	Thrombosis grade comparable to predicate. Weight changes of the implants comparable between test and control articles.
Visual/Dimensional Inspection	Visual inspection for extraneous matter, process and surface defects or defects that may cause trauma to vessels. Dimensional inspection per drawings.	No surface defects or visible droplets of coating on catheters. All catheters met dimensional specifications.
Air Ingress/Negative Collapse	Tests per ISO 10555.	Hub fittings do not allow air ingress and no evidence of lumen collapse.
Kink Resistance	Tests for kinks after distal tip of catheter is wrapped around a 0.25" diameter peg.	Device was resistant to kinking around small diameter turns per specification.
Tensile Strength/Elongation	Tensile testing performed per ISO 10555-1 on distal, mesial and proximal catheter sections after simulated use.	All catheters met minimum force breakage based on tube diameters specified in ISO 10555-1.
Liquid Leakage under Pressure/Leakage at Hub	Test for leakage at 300-320 kPa per ISO 10555-1.	No leakage from hub or catheter body.
Tip Stiffness	Test for stiffness per ASTM D747-10.	Tip stiffness was comparable that of the predicate devices.
Pressure vs. Flow Characterization	Flow rates measured at two typical pressures: 100 and 300 psi.	Flow rates reported in Instructions for Use at 100 and 300 psi.
Static Burst Pressure	Burst pressure tested per ISO 10555-1.	Maximum peak pressures all exceeded 300 psi.
Dynamic Flow	Product used with power injection to 750 psi.	No leaks, breaks or occluded lumens at 750 psi.

Test	Test Method Summary	Results
Flexibility Fatigue and Profile	Worst case bend of 90° with an 8-fold safety factor for repetitions.	All catheters showed no signs of cracks or breakage post worst case simulated use.
Shape Retention	Catheters must maintain a specified % of initial angle after water-bath conditioning and insertions and withdrawals of a guidewire. Tensile strength must meet original specs after shaping.	All catheters maintained specified tip angle after steam shaping, water bath conditioning and simulated use of guidewires. Tensile testing after tip shaping passed minimum tensile strength requirements.
Torque to Failure	Torque turns to failure in an anatomical model to provide a 4-fold safety factor.	All catheters showed no signs of breakage, twists or collapsed lumens after specified number of torque turns.
Coating Lubricity and Durability	Frictional force of uncoated and coated catheters determined.	All catheters met specified frictional forces.
Coating Integrity	Coating uniformity and integrity visually examined on dyed samples after simulated use in a tortuous path.	All samples showed acceptable coating coverage post simulated use.
Particulates	Particulates counted in sizes $\geq 10\mu\text{m}$, 25 μm , 50 μm , 65 μm , 100 μm , 200 μm and 500 μm after inserting a guidewire and advancing the catheter through a guide catheter multiple times.	The test and predicate catheters had comparable numbers of particles in each size range.
Chemical compatibility	Catheters were exposed to saline and contrast agent/saline solutions and examined for degradation.	All catheters showed no signs of degradation, corrosion or physical decomposition.
Latex Content	Tested for trace latex proteins per ASTM D6499-07.	No detectable traces of latex found.
Corrosion Resistance	Test for corrosion resistance per ISO 10555-1.	No signs of corrosion on metallic components of catheters.
Radiopacity	Catheters and predicates evaluated by physicians under simulated use in human cadavers.	Both test and predicate catheters had acceptable radiopacity.

Test	Test Method Summary	Results
MRI Compatibility	Catheters contain conducting and magnetic materials and should not have exposure to MRI.	Catheters are labeled MRI Unsafe on IFU.
Simulated Use	Anatomical model designed for tortuous anatomy used for simulated use testing.	Catheters and predicate devices had comparable Likert scores in terms of Guidewire tracking and guide catheter movement. Interventional devices successfully deployed.
Cadaver Testing	Cadaver used to evaluate catheter and predicate devices by physicians for performance, access time, and ability to deploy and retrieve interventional devices.	Test and predicate devices both exhibited comparable performance with similar access time to the designated target.
Packaging Testing	Packaging evaluated for pouch seal strength per ASTM F 88-00 and leak tests (bubble test) per ASTM F 2096-04.	All sterile barrier pouches met minimum seal strength and showed no bubbles under leak test conditions.
Shelf Life Testing	Functions testing repeated post accelerated aging and room temperature confirmatory storage.	Shelf life testing in progress. Expiration date will be advanced as aging data are available to demonstrate package and product continues to meet specifications.

Conclusions:

Scientia Vascular, LLC has demonstrated that the Plato MICROCATH 27B Microcatheter is substantially equivalent in fundamental design, technology, function, device materials, packaging, sterilization, operating principles and the indications for use as the ev3 predicate device, and represents a modification in design and materials to the existing MICROCATH 27 family of products. The testing supports a determination of substantial equivalence to products previously cleared by FDA.